

Sent: 9/18/2019 3:40:04 PM
Subject: Q&A: TCEQ toxicologists address proposed ethylene oxide limit

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Agency accepting comments until Sept. 26 on change

By Andrew Keese, TCEQ Media Relations

TCEQ's Toxicology, Risk Assessment, and Research Division has proposed a 4 parts per billion health-protective concentration for ethylene oxide. The proposed value, if finalized, would be used as a screening level for air permits. TCEQ is currently welcoming comments until Sept. 26 on the proposed ethylene oxide limit.

Drs. Michael Honeycutt, the division director, and Sabine Lange, the Toxicology Section manager, answered the following questions about the proposed change, including how it was developed and why:

1. Can you provide an overview of what's next after the deadline for comments? What's the general process?

After the Sept. 26 deadline, TCEQ will consider the public comments, revise the assessment as needed, and then post the assessment as final, along with responses to comments. Once finalized, TCEQ will use the ethylene oxide effect screening level in the review of air permits for new facilities in Texas. The newly derived ethylene oxide long-term ESL will replace the one that TCEQ is currently using, which is set at 1 part per billion. TCEQ's proposed long-term ESL is 4 ppb and supported by robust science.

2. I know it says so on the proposal, but can you summarize exactly why TCEQ concluded that EPA had overestimated the cancer potency of ethylene oxide due to what TCEQ called the use of an improperly validated, unconventional mathematical model?

To derive the ethylene oxide cancer dose-response assessments, both EPA and TCEQ used data from a United States-based group of workers who were exposed to very high concentrations of ethylene oxide for many years and who experienced an increased rate of lymphoid cancers. From this data, both TCEQ and EPA had to estimate what the risk would be to a person who was exposed to typical environmental concentrations of ethylene oxide, which can be millions of times lower than the occupational levels the workers had been exposed to.

The first step in this extrapolation is to determine how the chemical could cause cancer: In this case, ethylene oxide can cause cancer by causing damage to DNA. Based on that mechanism, the standard and conventional risk assessment method is to use a mathematical dose-response model that essentially draws a best-fitting straight line from the high dose data (from the worker exposure study) down to low doses (so it is applicable to ambient exposures). This is the standard method that TCEQ used, and using that method, agency toxicologists were able to accurately predict the number of cancers that were observed in the worker study. In contrast, instead of using the standard straight-line risk model, EPA chose to assume that low doses of ethylene oxide are

more potent than high doses for causing cancer (this is called a supra-linear model, and is the unconventional model that TCEQ referred to). EPA's model was shown by TCEQ to significantly over-predict the number of cancers that were observed in the worker study, which is how we mathematically demonstrate that EPA's method over-predicts cancer risk.

In addition, the human body naturally produces low levels of ethylene oxide, with background levels being higher in smokers. Using EPA's risk assessment, the background levels of ethylene oxide in the population would be predicted to cause more lymphoid cancer than is actually observed in the general population (and ignoring any other potential cause of lymphoid cancer). In this way, we also know that EPA's model over-estimates the cancer potency of ethylene oxide.

3. Potentially, how much ethylene oxide would petrochemical plants be able to emit if the proposal goes through?

If finalized, this new effect screening level for ethylene oxide to be used in air permitting of new facilities would be similar to the one that TCEQ is currently using (see the response to the first question).

4. Why is TCEQ's assessment more accurate than that of EPA?

As noted in the response to the second question, TCEQ's model accurately predicts the lymphoma cancer risk that was documented in the underlying U.S. worker study, while EPA's model was mathematically demonstrated by TCEQ to significantly over-predict risk.

5. Some of the concerns expressed by environmental groups include: That the goal is to "turning back the clock on progress for public health protection;" that using TCEQ's value instead of the IRIS value would likely lead TCEQ to try to ignore health threats from all EtO-emitting facilities, including chemical and petrochemical plants in Texas; and that TCEQ appears to ignore the breast cancer research, that it focuses on a males-only occupational study to set its value, which is based on lymphoid cancer risk.

True progress in the protection of public health cannot be made based on demonstrably flawed science, but rather must be made on accurate assessments of the risks posed by chemicals. Only then can chemical exposures of the public be appropriately prioritized for mitigation to achieve the greatest reductions in real health risk. Otherwise, public, government, and industry efforts and resources are wasted on addressing unrealistic risks created by flawed science. The TCEQ assessment, which more accurately predicts cancer risk than EPA's (as discussed above), will allow Texas to better assess potential health risks posed by ethylene oxide-emitting facilities in Texas and act accordingly.

The TCEQ assessment is not based on a males-only study but rather the same NIOSH cohort used by EPA, which is composed of about half female workers. The TCEQ assessment does evaluate breast cancer as a potential endpoint, and agency toxicologists anticipate that even more information on breast cancer risk will be included in the final assessment document. Lymphoid cancer, however, is the primary endpoint in TCEQ's assessment and the primary contributor to ethylene oxide risk in EPA's assessment. Based on the dose-response analyses for lymphoid cancer, females appear to have less risk from ethylene oxide exposure than males. Therefore, using risk results based on males results in even greater protection for females.

6. EPA said the greatest risk is for people who have lived near a facility releasing EtO into the air for their entire lifetime and that the cancer risk is greater for children than for adults. This is because ethylene oxide can damage DNA. For everyone, including children, risks would decrease with decreased exposure. Does TCEQ's assessment take this into account, especially given the number of facilities in the state?

Yes, risks are greatest for people who are exposed to EtO for their entire lifetime, and lifetime risks are greater when exposure begins in childhood. To ensure that children are also protected, EPA and TCEQ both use age adjustment factors.

7. What could be the consequences of what TCEQ considers an overestimation of risk by EPA?

Please refer the response to the fifth question, [as well as to the FDA](#).

8. What are current guidelines being applied in Texas?

The current long-term value for ethylene oxide is 1 ppb, which is an interim value intended to be conservative until a fully scientifically rigorous assessment with extensive dose-response analyses could be conducted. By TCEQ having done so, such an assessment fully supports the proposed value of 4 ppb.

9. When is the last time TCEQ disagreed with an EPA assessment? Is this unusual?

TCEQ works with EPA daily on a wide range of issues. TCEQ and EPA typically agree on issues, but sometimes do not. It's not unusual for states to disagree with EPA. However, in this case, TCEQ demonstrated that its assessment more accurately predicts the cancer potency of ethylene oxide than the EPA's assessment (see answers given above).

10. Do you have a different proposal or guideline for workers?

TCEQ does not regulate occupational exposures.

11. TCEQ's proposal comes at a time when other states, starting with Illinois, are moving to enact stricter standards. Any thoughts on that?

TCEQ began considering its currently proposed ethylene oxide assessment in early 2017 and put out a public request for information on Aug. 16, 2017. It is the agency's understanding that EPA collected the initial ethylene oxide air samples around the Willowbrook, Ill., facility in May 2018. This May 2018 EPA sampling event was the beginning of Illinois' (and other state's) ethylene oxide activities.